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# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

## 1.0 submitter's information

AUG 18 2009


Name: Andon Health Co., Ltd.
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Phone number: 86-22-6052 6161
Fax number: 86-22-6052 6162
Contact: Liu Yi

Date of Application: 05/27/2009

## 2.0 Device information

Trade name: Semi Automatic Electronic Blood Pressure Monitor
Common name: Noninvasive blood pressure measurement system
Classification name: Noninvasive blood pressure measurement system

## 3.0 Classification

Production code: DXN- Noninvasive blood pressure measurement system.
Regulation number: 870.1130
Classification: II
Panel: Cardiovascular

## 4.0 Predict device information

Manufacturer: Andon Health Co., Ltd.
Device: KD-391 Semi Automatic Electronic Blood Pressure Monitor
510(k) number: K080326

## 5.0 Device description

KD-3917 and KD-3909 Semi Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

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It is designed and manufactured according to ANSI/AAMI SP10--manual, P2/4 electronic or automated sphygmanometers.

The operational principle is based on oscillometric and silicon integrate pressure sensor technology, the result will be shown on a LCD with an electronic interface module; the result can also be classified and displayed by the function of blood pressure classification indicator, the memory capability of KD-3909 is 2×60 times, the memory capability of KD-3917 is 60 times. If any irregular heartbeat is detected, it can be shown on the LCD. KD-3909 also has the function of averaging the last three measurements.

## 6.0 Intended use

KD-3917 and KD-3909 Semi Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

The intended use and the indication for use of KD-3917 and KD-3909, as described in their labelings are the same as the predict device KD-391.

## 7.0 Summary comparing technological characteristics with predicate device

| Technological Characteristics | Comparison result |
|---|---|
| Design principle | Identical |
| Appearance | Similar |
| Patients contact Materials | Identical |
| Performance | Similar |
| Biocompatibility | Similar |
| Mechanical safety | Identical |
| Energy source | Identical |
| Standards met | Identical |
| Electrical safety | Identical |
| EMC | Identical |
| Function | Similar |

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## 8.0 Performance summary

KD-3917 and KD-3909 Semi Automatic Electronic Blood Pressure Monitor conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).
- AAMI SP10:2002, Manual, electronic or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A1:2003 –, Amendment 1 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A2:2006 –, Amendment 2 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.

## 9.0 Comparison to the predict device and the conclusion

Our device KD-3917 and KD-3909 Semi Automatic Electronic Blood Pressure Monitor is substantially equivalent to the Semi Automatic Electronic Blood Pressure Monitor KD-391 whose 510(k) number is K080326.

KD-3917 and KD-391 are very similar in the intended use, the design principle, the material, the energy source and the applicable standards. Only their appearance is different. The Environmental parameters is changed, the operational range for humidity (<90%) are changed from the predict device whose operational range for humidity is <80%. The performance parameter of cuff pressure range and overpressure limit are different from the predicted device KD-391. The pulse rate range is changed from 30-180 times/min to 40-180 times/min, KD-3917 also adds a new cuff.

KD-3909 and KD-391 are very similar in the intended use, the design principle, the material, the energy source and the applicable standards. Only their appearance and some functions such as 2×60 times memory and averaging the last three measurements are different. The Environmental parameters is changed, the operational range for humidity (<90%) are changed from the predict device whose operational range for humidity is <80%. The performance parameter of cuff pressure range and overpressure limit are different from the predicted device KD-391. The pulse rate range is changed from 30-180 times/min to 40-180 times/min, KD-3909 also adds a new cuff.

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However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Andon Health Co., Ltd.
c/o Mr. Liu Yi
No 31 Changjiang Road
Nankai District, Tianjin
China 300190

AUG 18 2009

Re: K091739
Trade/Device Name: KD-3917, KD-3909 Semi Automatic Electronic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: undated
Received: July 21, 2009

Dear Mr. Yi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Statement of Indications for Use

**510(k) Number :** K091739

**Device name:** KD-3917 and KD-3909 Semi Automatic Electronic Blood Pressure Monitor

**Indications for use:**

KD-3917 and KD-3909 Semi Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

Prescription use _____ AND/OR Over-The-Counter Use YES
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091739